TEMPLATE WORDING FOR THE EXPEDITED ADVERSE EVENT REPORTING SECTION OF DAIDS-SPONSORED PROTOCOLS

[FOR USE WITH The Manual for Expedited Reporting of Adverse Events to DAIDS *DATED MAY 6, 2004*]*

Expedited Adverse Event Reporting to DAIDS

The expedited adverse event (EAE) reporting requirements and definitions for this study and the methods for expedited reporting of adverse events (AEs) to the DAIDS Regulatory Compliance Center (RCC) Safety Office are defined in "The Manual for Expedited Reporting of Adverse Events to DAIDS" (DAIDS EAE Manual), **dated May 6, 2004**. The DAIDS EAE Manual is available on the RCC website: http://rcc.tech-res-intl.com/. *[If the DAIDS EAE Manual is also available in the Study Operations Manual, please indicate here.]*

AEs reported on an expedited basis must be documented on the DAIDS Expedited Adverse Event Reporting Form (EAE Reporting Form) available on the RCC website: http://rcc.tech-res-intl.com. *[If the EAE Reporting Form is also available in the Study Operations Manual, please indicate here.]*

EAE Reporting Requirements for this Study

EAE Reporting Level

This study uses the *[Insert the reporting level:* Standard, Intensive, or Targeted] Level of expedited AE reporting as defined in the DAIDS EAE Manual. *[If applicable, include any additional grades or types of AEs to be reported to DAIDS on an expedited basis HERE.]*

Study Agents for Expedited Reporting to DAIDS

The study agents that must be considered in determining relationships of AEs requiring expedited reporting to DAIDS are: *[Insert a list of study agent(s) or indicate drug categories to be considered. Generic or International Non-proprietary Names (INNs) must be listed, but protocol-specific codes or abbreviations for use by sites may be also specified.]*

Grading Severity of Events

The Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events (DAIDS AE Grading Table), Version 1.0, December, 2004, must be used and is available on the RCC website at http://rcc.tech-res-intl.com/. *[If the DAIDS AE Grading Table is also available in the Study Operations Manual, please indicate here.]*

[A protocol team developing protocol-specific adverse event grading criteria NOT found in the DAIDS AE Grading Table would define those additional or modified parameter(s) with grades here or in an appendix to this protocol.]

* Red text indicates places where protocol-specific information is to be inserted.

EAE Reporting Periods

AEs must be reported on an expedited basis at the *[Re-state the reporting level chosen above]* Level during the Protocol-defined EAE Reporting Period, which is: *[Choose one of the following:]*

- The entire study duration for an individual subject (from study enrollment until study completion or discontinuation of the subject from study participation for any reason).

OR

- The entire study duration for an individual subject (from study enrollment until study completion or discontinuation of the subject from study participation for any reason) and for a period of *[please define]* after the subject's last study visit has been completed. *[NOTE: In this instance, the consent MUST state that active follow-up for possible EAEs will extend beyond the last scheduled study visit for the individual subject.]*

After the end of the Protocol-defined EAE Reporting Period stated above, sites must report serious, unexpected, clinical suspected adverse drug reactions if the study site staff becomes aware of the event on a passive basis, i.e., from publicly available information.

* Red text indicates places where protocol-specific information is to be inserted.